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Mr. Jeffrey Sampson
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LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS) DECISION SUMMARY

Dear Jeff:

Further to the last meeting of the LIMS Team on July 17, 1998, I thought it appropriate to briefly summarize our LIMS decision making process throughout the last year.

I was impressed throughout the decision making process with the openness with which you, as Team Leader, and the LIMS Team were willing to consider all of the issues brought to the table. This included but was not limited to the system platform, initial and final phases of the project, expansion of the system from Philip Morris USA R&D to all of Philip Morris USA, the evolving regulatory issues, and the changes within the LIMS industry itself. Everyone approached the project with a completely open mind and no biases whatsoever.

A series of Joint Application Design meetings were held with a cross-section of people in each of the laboratories. The results of these discussions were used in my needs assessment and our writing of the request for proposals (RFP).

Initially ALL of the LIMS vendors were considered and the strengths and weaknesses of each of them were discussed fully. While many of the LIMS offerings wold meet most of the needs of Philip Morris USA, we focused on those vendors whose products would help the laboratories enforce Good Laboratory Practice (GLP) and Good Automated Laboratory Practice (GALP). Financially weak vendors were eliminated almost immediately.

While there is currently no regulation in the tobacco industry, we did center our attention on those vendors with extensive experience in regulated industries

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such as pharmaceuticals because the systems from these companies are generally better at enforcing good laboratory practices (small "g").

Out of the over fifty LIMS vendors in business, we narrowed the list to the following (in alphabetical order):

- Baytech
- Beckman Coulter, Inc.
- Blaze Systems
- Compex
- Hewlett Packard
- LabSystems
- LabVantage Solutions
- LabWare
- LabWorks
- L.I.M.S., Ltd.
- Perkin Elmer
- Quality Software International
- Telecations

Advantages and disadvantages of each was discussed and, based on my knowledge of each of the vendors and their current LIMS and their suitability to the needs of Philip Morris USA, the list was quickly narrowed to Hewlett Packard, LabSystems, and LabWare. Beckman Coulter was added to the short list later.

Each of these vendors was invited to give a one-day demonstration of the capabilities of their software. As a result of that demonstration, Hewlett Packard was eliminated from the mix and was not invited to respond to the RFP. There is extensive proprietary information on the manner in which the R&D labs are run and it was felt that the fewer vendors to which it was sent, the better.

Beckman Coulter, LabSystems, and LabWare responded to the RFP. As a result of these responses LabWare was eliminated. The major reasons for this was that the very small size of LabWare (20 people total), prevents them from fully servicing the needs of a company and project the size of the Philip Morris implementation. This is clearly stated in their response to the RFP. Their proposed solution of hiring outside unknown subcontractors is unacceptable.

The two remaining vendors, Beckman Coulter and LabSystems were each invited to demonstrate their system AS IT APPLIES TO PHILIP MORRIS. They

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were to show the capabilities of their system as detailed in the RFP. In addition a specific, mandatory, demonstration script was given to each vendor six weeks in advance of the two-day demonstration. Some of each vendor's references were checked as well.

As a result of these extensive demonstrations, the final choice of the LabSystems Sample Manager LIMS was quite clear. LabSystems was able to demonstrate to our satisfaction that not only could they meet all of our needs, but, in many cases, exceed them. They showed this, not simply by words, but by actually configuring their system to show the LIMS Team and others in attendance, how it could perform each function. Some areas will require clarification during JAD meetings and workshops prior to and during the system implementation but there seems to be no insurmountable problems.

Their implementation philosophy uses a joint project team containing both a LabSystems Project Team and a Philip Morris Project Team, each with its own independent Project Manager. I am satisfied that the LabSystems implementation model will meet the needs and methods of working that Philip Morris practices. Their system is widely installed in highly regulated industries such as pharmaceuticals. Their system enforces GLP, GALP, cGMP, and GAMP.

It is unfortunate that Beckman Coulter was not able to demonstrate their ability to comply with the needs of Philip Morris R&D as detailed in the RFP. Basing an important decision such as this LIMS decision on faith is irrational. The three sales people received no support whatsoever from either the Beckman implementation or support team. Through news releases on the Beckman Instruments purchase of Coulter Instruments, it is my interpretation that the focus of Beckman Coulter will focus more on the biotech product line than the instrument sales, of which LIMS is a part. This may be the underlying reason that so little effort was put into the demo. It was made abundantly clear that, based upon the demo, Beckman could not possibly address the current or future needs of Philip Morris. I was personally shocked and embarrassed at how little effort was put into the demonstration. It almost seemed that Beckman Coulter expected to win the contract award on their brand name alone. This may have been the case in the past, but no more. Many past users have abandoned their system in favor of replacing it altogether with another brand, more modern in its screen use, configuration, and flexibility. Using a proprietary language to write even the simplest of calculations is not acceptable to the current user community. Not one of the three people presenting the demonstration was able

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to insert even a simple wet weight minus dry weight calculation into the system. The question was legitimately raised that if three people familiar with using the system are unable to insert this simplest of calculations, how could the system be configured as the Philip Morris needs change. This seems to coincide with my experience of Beckman users that once the system is fully configured it is difficult to reconfigure, as the laboratory needs change.

It is my belief that you, Jeff, as Team Leader, and the members of the LIMS Team, after reviewing all of the possible alternatives, made the correct decision in choosing LabSystems Sample Manager as the new Philip Morris Laboratory Information Management System.

If additional clarification is needed on the LIMS decision mechanism, please do not hesitate to contact me.

I must say, in closing, that this group of LIMS Team members has been absolutely great to work with. Each member was attentive and remained focused and on-track. Every suggestion was well thought out and problems were addressed quickly and completely. No one member dominated the conversations nor tried to impose their will on others. I know that this is the way it is supposed to work, but, unfortunately, it doesn't always come out this way.

I know that I will be keeping in touch with you throughout the implementation process but I want to thank you for doing such an outstanding job. I know that all of Philip Morris will benefit from your actions.

Please extend my heartfelt thanks to everyone on the LIMS Team.

Very truly yours,

Martin Goffman, Ph.D.
Principal

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